

**AUROQUIL COUGH NIGHTTIME COUGH RELIEF - dextromethorphan hbr and doxylamine succinate solution**

**Aurohealth LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Drug Facts**

**Active ingredients (in each 30 mL dose cup)**

Dextromethorphan HBr USP 30 mg .....	Cough suppressant
Doxylamine succinate USP 12.5 mg .....	Antihistamine

**Purpose**

**Uses**

temporarily relieves cold symptoms:

- cough
- runny nose and sneezing

**Warnings**

**Do not use**

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleep

**Ask a doctor before use if you have**

- glaucoma
- excessive phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

**When using this product**

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts.

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses (120 mL) (8 TBSP) per 24 hours
- mL = milliliter; TBSP = tablespoon

adults and children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- **when using other Daytime or Nighttime products, carefully read each label to insure correct dosing**

**Other information**

- **each 30 mL dose cup contains:** sodium 35 mg
- store at 20° to 25°C (68° to 77°F)

**Inactive ingredients**

alcohol, anhydrous citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

**Questions or Comments?**

**1-855-274-4122**

**Distributed by:**

Aurohealth LLC.  
2572 Brunswick Pike  
Lawrenceville, NJ 08648

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 6 FL OZ (177 mL Bottle)**

**AUROHEALTH**

Compare to the active ingredients  
in Vicks<sup>®</sup> NyQuil<sup>®</sup> Cough<sup>\*</sup>

**NDC 58602-132-20**

**AuroQuil**  
**COUGH**  
**Nighttime Cough Relief**

Each dose (per 30 mL) (2 TBSP) of oral solution contains:  
30 mg - Dextromethorphan HBr USP (Cough suppressant)  
12.5 mg - Doxylamine succinate USP (Antihistamine)

- **Cough**
- **Sneezing, Runny Nose**

*Alcohol 10%*

*Cherry Flavor*

**6 FL OZ (177 mL)**

## Front

**Tamper Evident: Do not use if printed shrinkband is missing or broken.**

Failure to follow these warnings could result in serious consequences

3001000158



\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Cough

**Distributed by:** Aurohealth LLC.  
2572 Brunswick Pike  
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LOT:

EXP:



Lift Here for continued **Drug Facts**

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Active ingredients (in each 30 mL dose cup)	Purpose
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## Back

### Drug Facts (continued)

or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

- to make a child sleep

#### Ask a doctor before use if you have

- glaucoma
- excessive phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
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**Ask a doctor or pharmacist before use if you are taking** sedatives or tranquilizers.

### Drug Facts (continued)

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## Bottom Ply

### Drug Facts (continued)

**If pregnant or breast-feeding**, ask a health professional before use.

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### Drug Facts (continued)

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### PARENTS:

Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 8 FL OZ (236 mL Bottle)**

**AUROHEALTH**

Compare to the active ingredients

in Vicks® NyQuil® Cough\*

NDC 58602-132-18

**AuroQuil**  
**COUGH**  
**Nighttime Cough Relief**

Each dose (per 30 mL) (2 TBSP) of oral solution contains:  
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- Cough
- Sneezing, Runny Nose

Alcohol 10%

Cherry Flavor


8 FL OZ (236 mL)

**Front**

3001000159

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LOT:   
EXP:

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NDC 58602-132-18

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- ◆ Cough
- ◆ Sneezing, Runny Nose

**Cherry Flavor** 

**Alcohol 10%**      **8 FL OZ (236 mL)**

Lift Here for continued **Drug Facts** 

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredients (in each 30 mL dose cup)</b>	
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**Drug Facts** (continued)

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**Drug Facts** (continued)

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## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 12 FL OZ (354 mL Bottle)

### AUROHEALTH

Compare to the active ingredients  
in Vicks® NyQuil® Cough\*

NDC 58602-132-16

### **AuroQuil COUGH Nighttime Cough Relief**

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- Cough
- Sneezing, Runny Nose

*Cherry Flavor*

**Alcohol 10%**

**12 FL OZ (354 mL)**

**Drug Facts** (continued)  
or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**  
 ■ use dose cup or tablespoon (TBSP) ■ do not exceed 4 doses (120 mL) (8 TBSP) per 24 hours ■ mL = milliliter; TBSP = tablespoon  
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 2572 Brunswick Pike  
 Lawrenceville, NJ 08648

LOT:   
 EXP:



**AUROHEALTH**

Compare to the active ingredients in Vicks® NyQuil® Cough\*

**NDC 58602-132-16**

**AuroQuil**

**COUGH**

**Nighttime Cough Relief**

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**Cherry Flavor**

**Alcohol 10%**      **12 FL OZ (354 mL)**

**Drug Facts**

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**Keep out of reach of children.** In case of overdose, get medical help

## AUROQUIL COUGH NIGHTTIME COUGH RELIEF

dextromethorphan hbr and doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-132
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>CHERRY</b> (UNII: BUC5I9595W)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

### Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-132-20	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021
2	NDC:58602-132-18	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021
3	NDC:58602-132-16	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/27/2015	09/01/2021

**Labeler** - Aurohealth LLC (078728447)

**Registrant** - Aurohealth LLC (078728447)

### Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(58602-132)

Revised: 11/2020

Aurohealth LLC